

1 REMARKS

2 Status of the Claims

3 Please cancel Claims 2 and 6.

4 Please amend Claims 1, 10, 11, 21, 25, 52, and 58.

5 Claims 1, 4, 5, 7-27 and 52-58 are pending in the present application, Claims 3 and 28-51
6 having been previously canceled, and Claims 2 and 6 having been canceled herein. Claim 52 has
7 been amended to correct a grammatical error, and Claims 1, 10, 11, 21, 25, and 58 have been
8 amended in order to place the claims in better condition for appeal.

9 Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

10 The Examiner has rejected Claims 1-2, 4-20, 21-27 and 53 under 35 U.S.C. § 112, second
11 paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject
12 matter which applicants regard as the invention. More specifically, the Examiner indicates that the
13 claims including the means plus function language improperly modify the “means for” phrase by
14 reciting significant structure (citing MPEP 2181). The Examiner explains that including such
15 modifying structural language makes it unclear if applicants intended to invoke the means for
16 limitation.

17 With respect to Claims 1-2 and 4-20, the means plus function language stated:

18 *means for preventing tactile detection of a simulated patent skull suture in the model, while*
19 *enabling the simulated patent skull suture to be visually detected based upon an appearance of the*
20 *simulated patent skull suture in an ultrasound image of said model, said means comprising a second*
21 *material that is selected to have an echogenicity substantially different than an echogenicity of said*
22 *first material.*

23 Applicants understand the Examiner’s position that the use of the means plus function clause
24 is improper per the third prong of the analysis discussed in MPEP 2181 (i.e., the means plus function
25 clause improperly includes modifying language). The amendment to Claim 1 presented herein
26 eliminates the means plus function clause, and thereby obviates the rejection under 35 U.S.C. § 112,
27 second paragraph. The amendment introduces subject matter from Claims 2 and 6 into Claim 1 (thus
28 the amendment does not introduce either new matter, or present a new issue). Note that Claim 1 as
29 amended recites a second material that enables the simulated patent skull sutures to be identified in
30 an ultrasound image while also preventing the simulated patent skull suture from being identified by

1 touch (thus, the concept defined in Claim 1 as amended is related to the improperly recited means
2 plus function language; but is recited using structure rather than means plus function). Applicants
3 respectfully request that the Examiner enter this amendment, even if the Examiner does not believe
4 the amendment places the case in condition for allowance, in order to place Claim 1 in better
5 condition for appeal, by removing the 35 U.S.C. § 112 issue associated with this claim.

6 With respect to Claims 21-26, the means plus function language stated:

7 *means for selectively modifying the model between training sessions by enabling a*
8 *filler material to be added within at least one selected opening, the filler material having an*
9 *echogenicity that is generally similar to that of the portions of the model not corresponding to the*
10 *simulated skull suture, so that each opening in which the filler material is added simulates a fused*
11 *skull suture in an ultrasonic image, the model being modified between training sessions by removing*
12 *the filler material from the at least one opening and adding the filler material within at least one*
13 *other different opening*

14 Applicants understand the Examiner's position that the use of the means plus function clause
15 is improper per the third prong of the analysis discussed in MPEP 2181 (i.e., the means plus function
16 clause improperly includes modifying language). The amendment to Claim 21 presented herein
17 eliminates the means plus function clause, and thereby obviates the rejection under 35 U.S.C. § 112,
18 second paragraph. The amendment does not introduce either new matter, or present a new issue.
19 Note that Claim 21 as amended recites a filler material that enables the simulated patent skull sutures
20 to be modified into simulated fused skull sutures, by replacing the original hypoechoic material in an
21 opening with the filler material (thus, the concept defined in Claim 21 as amended is related to the
22 improperly recited means plus function language; but is recited using structure rather than means plus
23 function). Applicants respectfully request that the Examiner enter this amendment, even if the
24 Examiner does not believe the amendment places the case in condition for allowance, in order to
25 place Claim 21 in better condition for appeal, by removing the 35 U.S.C. § 112 issue associated with
26 this claim.

27 With respect to Claim 27, it appears that Claim 27 has been improperly grouped with
28 Claims 1-2, 4-20, 21-26, and 53; as Claim 27 does not include *any* means plus function language.
29 Thus, the rejection of Claim 27 under 35 U.S.C. § 112, second paragraph is not appropriate, and the
30 rejection should be withdrawn.

With respect to Claim 53, applicants have *not* amended Claim 53, because the means plus function language does not recite any significant structure, and thus the means plus function clause is proper according to the test defined in MPEP 21818. The means plus function clause is lengthy, but recites a function without reciting significant structure. More succinctly stated, the means plus function clause recites means for modifying a simulated patent skull suture to create a simulated fused skull suture. The additional text simply defines a simulated fused skill suture. Claim 53 would thus appear to present a properly constructed means plus function clause, and its rejection under 35 U.S.C. § 112, second paragraph should be withdrawn.

Claims Rejected Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected Claim 58 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and as failing to comply with the enablement requirement. The Examiner explains that the claims contain subject matter which was not described in the specification in such a way as to either reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention or to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, the Examiner explains that Claim 58 sets forth limitations of a kit and instructions for selectively adding a filler material that is not disclosed in the specification as it was originally presented.

Accordingly, applicants have amended Claim 58 to delete language reciting both a “kit” and “instructions.” Applicants respectfully request that the Examiner enter this amendment, even if the amendment does not place the case in condition for allowance, in order to place this claim in better condition for appeal, by removing the 35 U.S.C. § 112 issue associated with this claim.

Claims Rejected Under 35 U.S.C. § 103(a)

Claims 1, 2, 4-27, and 52-58 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,708,836 (Gain et al. - hereinafter referred to as “Gain”) in view of NPL #1, “Infant Skull Model and Sculpted Head” (retrieved on June 09, 2002) and further in view of U.S. Patent Publication No. 2003/0208101 (Cecchi).

Claims 14-17, 21-26 and 52-58 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gain in view of NPL #1, in view of U.S. Patent No. 5,609,485 (Bergman et al.) and further in view of Cecchi.

1 In the interest of reducing the complexity of the issues for the Examiner to consider in this
2 response, the following discussion focuses on independent Claims 1, 21, 27, 52-54, and 57-58. The
3 patentability of each remaining dependent claim is not necessarily separately addressed in detail.
4 However, applicants' decision not to discuss the differences between the cited art and each dependent
5 claim should not be considered as an admission that applicants concur with the Examiner's
6 conclusion that these dependent claims are not patentable over the disclosure in the cited references.
7 Similarly, applicants' decision not to discuss differences between the prior art and every claim
8 element, or every comment made by the Examiner, should not be considered as an admission that
9 applicants concur with the Examiner's interpretation and assertions regarding those claims. Indeed,
10 applicants believe that all of the dependent claims patentably distinguish over the references cited. In
11 any event, a specific traverse of the rejection of each dependent claim is not required, since
12 dependent claims are patentable for at least the same reasons as the independent claims from which
13 the dependent claims ultimately depend.

14 Comments Applicable to the Combination of Gain, NPL#1, and Cecchi

15 Gain discloses a model made of different materials for evaluating mechanical stresses on the
16 head during a crash (note that the different materials are selected so that the model realistically
17 responds to mechanical stress, and the appearance of those materials in an ultrasound image is not
18 relevant to Gain's function, nor is there any description in Gain as to how those materials would
19 appear in an ultrasound image), NPL #1 discloses a model of an infant head including patent skull
20 sutures, and Cecchi discloses modifying a distal portion of a catheter so that the distal portion can be
21 more readily observed in an ultrasound image. The Examiner's rejection appears to be that because
22 Cecchi discloses that materials can be manipulated to provide a desired appearance in an ultrasound
23 image, that it would have been obvious to the artisan of ordinary skill to incorporate the patent skull
24 sutures of NPL #1 into Gain, using materials selected such that the patent skull sutures are made of
25 different materials than other portions of the model so that the patent skull sutures are visible in an
26 ultrasound image.

27 Applicants respectfully disagree. Applicants respectfully request that the Examiner consider
28 the following. The cited art (Gain, NPL#1, and Cecchi) provides no evidence that the artisan of
29 ordinary skill recognized that providing a *medical training model that could be used to train*
30 *sonographers to detect craniosynostosis* represented a problem to be solved. While NPL#1 and Gain

1 provide models that can be used as visual aids for medical training, and Gain's model is specifically
2 constructed to realistically respond to the application of mechanical stresses, those models are not
3 designed to be examined using ultrasound. It is applicants' position that applying Cecchi's
4 manipulation of materials to control what can be observed in an ultrasound image to achieve a model
5 for training sonographers to detect craniosynostosis represents a combination that would not have
6 been obvious to the artisan of ordinary skill.

7 Even post *KSR*, it is recognized that it is important *to identify a reason that would have*
8 *prompted a person of ordinary skill in the relevant field to combine the elements in the way the*
9 *new invention does*. This is so because inventions in most, if not all, instances rely upon building
10 blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of
11 what, in some sense, is already known.

12 The *KSR* court recognized that while a rigid application of a teaching, suggestion, motivation
13 test was not necessary, that some inquiry as to why an artisan of ordinary skill would combine
14 references in a particular manner was appropriate, and that *market forces* could be applicable to that
15 issue (where strong market forces exist, it is more likely that an artisan would have made the
16 combination, and conversely, where weak demand is present, such combinations become less likely).

17 In context of the present application, *as no references directed to medical models for training*
18 *sonographers have been found during Examination*, it seems unreasonable to conclude that there is
19 strong market demand for medical models for training sonographers. It should also be noted that
20 whatever the total market demand for medical models for training sonographers is, the bulk of that
21 demand will logically be directed to models related to the most common uses of ultrasound.
22 Detection of craniosynostosis using ultrasound represents only a small part of ultrasounds' utility to
23 the medical profession, and the total market demand for medical models for training sonographers to
24 detect craniosynostosis is logically relatively small. Based on this market demand approach
25 discussed in *KSR*, the likelihood of the artisan of ordinary skill being motivated to combine the
26 references as suggested appears relatively low.

27 With respect to the question as to why the artisan of ordinary skill would modify Gain based
28 on Cecchi, the Examiner states *it would have been obvious to one of ordinary skill in the art to*
29 *manipulate the density of the second material, as taught by Cecchi, because it would enable the head*
30 *model to have the correct echogenic properties*.

1 The *correct echogenic properties* remark is significant. No one, other than applicants,
2 defined what the *correct echogenic properties* of a head model should be. Neither Gain nor NPL#1
3 require any particular *echogenic properties*. Gain requires that the material properties of the model
4 realistically respond to mechanical stresses. The *echogenic properties* of the materials are irrelevant.
5 Manipulating the *echogenic properties* of the materials in Gain's model will not improve Gain's
6 model with respect to its intended purpose, realistically responding to mechanical stresses. Cecchi
7 defines the *correct echogenic properties* for an embryonic catheter, but not for a medical model for
8 training sonographers to detect craniosynostosis. The suggested combination is impermissibly based
9 on hindsight, because hindsight has been used to define the *correct echogenic properties* of a head
10 model, not the prior art.

11 Comments Applicable to Bergman

12 Respectfully, applicants do not understand the Examiner's interpretation of the Bergman
13 reference (U.S. Patent No. 5,609,485). The Examiner has noted that Bergman discloses *selectively*
14 *modifying a model between training sessions by enabling a filler material to be added to an opening*.

15 Bergman discloses an ultrasound training model, based on a computer in which are stored
16 actual ultrasound images, a mannequin, and a sensor (a position sensor capable of accurately
17 determining the sensor's position relative to the mannequin) that simulates an ultrasound probe. The
18 student moves the sensor relative to the mannequin, and based on the sensor's position the computer
19 displays a previously obtained ultrasound image corresponding to the position of the sensor relative
20 to the mannequin. Note that no ultrasound image is actually being collected during the training
21 session, rather previously collected ultrasound images of actual humans (and not of the mannequin)
22 are displayed.

23 With respect to *selectively modifying a model between training sessions*, presumably the
24 recorded ultrasound images could be modified between sessions (although it does not appear that
25 Bergman discloses such a modification), however, applicants cannot find any mention of an opening
26 in the mannequin being modified between sessions to change the echogenicity of the opening.
27 Further, such a modification would not be logical, as the *echogenic properties* of the mannequin are
28 irrelevant, as no actual ultrasound data is being collected from the mannequin (only a relative
29 position, so previously record ultrasound images obtained from a real patient can be displayed).

1 The Examiner has specifically cited to 8:35-50 of Bergman as being particularly relevant.
2 Respectfully, that portion, reproduced below, does not appear relevant to the pending claims, and
3 does not disclose *selectively modifying a model between training sessions by enabling a filler*
4 *material to be added to an opening.*

5 As broadly depicted in FIG. 1, a simulated body 32 is provided, preferably a
6 mannequin, the simulated body 32 including a transmitter 34, as discussed in
7 further detail below. The transmitter 34 can be embedded in the body at any of
8 a plurality of desired locations, or can be attached outside of the body at any of
9 a plurality of locations. It is to be understood, however, that the simulated body
10 32 is necessary only when the invention is used for training. When used by a
11 trained practitioner for diagnosis, the transmitter 34 alone is necessary, without
12 requiring a simulated body (column 8, lines 30-40).

13 In accordance with the invention, a sensor is operable to detect data in relation
14 to a position of the sensor with respect to the transmitter. As is broadly
15 depicted in FIG. 1, a simulated ultrasound probe 36 is provided, containing a
16 sensor connected via cable 38 to a simulated ultrasound unit 40. The probe 36
17 is configured to be held by an operator/trainee, and be manipulated with six
18 degrees of freedom exactly the same as the actual ultrasound probe 26. The
19 probe 36 includes as the sensor a 6 DOF receiver 46, depicted broadly in FIG.
20 4 (column 8, lines 41-51).

21 Patentability of Independent Claim 1

22 Claim 1 has been amended to now recite a model for training ultrasound clinicians including
23 *at least one simulated patent skull suture comprising a second material and a scalp portion in which*
24 *each simulated patent skull suture is disposed, such that the scalp portion of the model is covered*
25 *with a layer of the second material, the second material extending beyond an opening in the first*
26 *material defining the simulated patent skull suture and covering at least a portion of the first*
27 *material, to prevent the simulated patent skull suture from being identified tactilely, the second*
28 *material having an echogenicity substantially different than an echogenicity of said first material,*
29 *such that each simulated patent skull suture can be readily distinguished in an ultrasound image of*
30 *said model.*

None of the cited art provides an equivalent to the specific structure underlined above. Even
if Cecchi's manipulation of materials was included in a medical model, there would be no need for
the second material to extend beyond the opening. Accordingly, the rejection of independent Claim 1
under 35 U.S.C. § 103(a) should be withdrawn because the cited art does not teach or suggest all of

1 the recitation of Claim 1 as now amended, and because the combination suggested impermissibly
2 relies on hindsight, as discussed above.

3 Since dependent claims inherently include all of the recitation of the independent claims from
4 which they ultimately depend, for at least the same reasons as noted above in connection with
5 independent Claim 1, the rejection of dependent Claims 4-20 should also be withdrawn.

6 Patentability of Independent Claim 21

7 The Examiner rejected Claim 21 for reasons generally similar to those applied in rejecting
8 Claim 1. However, Claim 21 has been amended in the present response to recite,

9 (a) *a substantially life size model of a human infant head, said model including a*
10 *plurality of openings;*

11 (b) *a solid or semi-solid hypoechoic material being included in each opening so*
12 *that the opening corresponds to a simulated patent skull suture, wherein the hypoechoic material*
13 *causes an echogenicity of the simulated skull suture to differ from that of portions of the model not*
14 *corresponding to the simulated patent skull suture, the difference enabling each simulated patent*
15 *skull suture to be identified in an ultrasonic image; and*

16 (c) *a filler material for selectively replacing the hypoechoic material included in*
17 *at least one selected opening, the filler material having an echogenicity that is generally similar to*
18 *that of the portions of the model not corresponding to the simulated skull suture, so that each opening*
19 *in which the filler material replaces the hypoechoic material simulates a fused skull suture in an*
20 *ultrasonic image, the model being modifiable between training sessions by replacing the hypoechoic*
21 *material with the filler material in at least one opening.*

22 None of the art cited by the Examiner teaches or suggests filling an opening in a model of a
23 skull with a filler material that has an echogenicity that is generally similar to that of the other
24 portions of the model, where the model can be modified between training sessions by removing the
25 filler material from at least one opening and adding the filler material to a different opening. This
26 approach is important so that a student who has gone through one training session will not simply
27 learn where the fused skull suture is located on the model skull and be able to use that knowledge to
28 indicate where the fused skull suture is located in a subsequent training session. By providing means
29 to change the location of the simulated fused skull suture between training sessions, the usefulness of
30 the model is greatly enhanced. The functionality is not obvious in view of the art and is clearly

supported in applicants' specification at page 16, line 25. Accordingly, the rejection of independent Claim 21 under 35 U.S.C. § 103(a) should be withdrawn because the cited art does not teach or suggest all of the recitation of Claim 21 as amended.

Since dependent claims inherently include all of the recitation of the independent claims from which they ultimately depend, for at least the same reasons as noted above in connection with independent Claim 21, the rejection of dependent Claims 22-26 should also be withdrawn.

Patentability of Independent Claim 27

The Examiner has rejected Claim 27 over the teaching of Gain, and the infant skull model of the NPL#1 reference. However, applicants respectfully disagree with this rejection for the following reasons.

As amended Claim 27 recites, "*a substantially life size model of a human infant head, said model including at least one simulated patent skull suture and at least one simulated fused skull suture*". Regardless of whether or not Gain's model includes a fused skull suture, the Examiner has not cited any reference including a simulated fused skull suture in a model of an infant skull, which is not surprising, since that condition is NOT considered a normal condition in an infant's or child's skull. Accordingly, it is further not surprising that none of the references teach or suggest how such a simulated fused skull suture on a model of a skull might be visually detected in an ultrasound image of an ultrasound trainer, as recited in this claim. Thus, it should be apparent that Claim 27 is novel and non-obvious in view of the art cited. For this reason, the rejection of independent Claim 27 under 35 U.S.C. § 103(a) should be withdrawn because the cited art does not teach or suggest all of the recitation of Claim 27.

Patentability of Independent Claim 52

Claim 52 recites an ultrasound trainer including an infant head model with a simulated fused skull suture and a simulated patent skull suture, where the echogenicity of the fused and patent sutures are different enough to enable them to be distinguished in an ultrasound image.

The Examiner has asserted that the materials disclosed by Gain have different echogenic properties and thus would be distinguishable in an ultrasound image. The Examiner has not provided any evidentiary support for this. Applicants are not disputing that materials have echogenic properties, only that the materials disclosed by Gain would be sufficient to enable simulated fused and patent skull sutures to be differentiated. Some of the materials (the polymers) disclosed by Gain

are similar to materials disclosed by applicants for simulating a fused skull suture (elastomers), however, Gain does not disclose any material similar to the starch/glue mixture used to simulate the patent skull sutures. Absent any actual evidence that the difference in echogenicity of oil/silicone mixtures and epoxy resin is sufficient that such materials can be used to generate a fused skull suture and a patent skull suture that can be distinguished in an ultrasound image, this rejection is unwarranted.

With respect to the Bergman reference, as discussed above the Bergman reference (U.S. Patent No. 5,609,485) **DOES NOT** disclose *selectively modifying a model between training sessions by enabling a filler material to be added to an opening* (at least based on 8:35-50; applicants reviewed Bergman in detail and cannot identify any other portion of the reference disclosing such modification). Accordingly, the cited combination of Bergman and Gain is not a valid rejection.

Finally, as discussed above in detail, modifying Gain based on Cecchi is not obvious, because the prior art simply has not recognized the value of applying the concepts disclosed by Cecchi to medical training models for ultrasound in general, and models for detecting craniosynostosis in particular.

Accordingly, the rejection of independent Claim 52 under 35 U.S.C. § 103(a) should be withdrawn, because the cited art does not teach or suggest all of the recitation of Claim 52 as now amended.

Patentability of Independent Claim 53

Claim 53 similarly recites *reversibly modifying one or more selected simulated patent skull sutures to create one or more simulated fused skull sutures that can readily be detected in an ultrasound image*.

As discussed above in detail, Bergman does not disclose that element.

Accordingly, the rejection of independent Claim 53 under 35 U.S.C. § 103(a) should be withdrawn because the cited art does not teach or suggest all of the recitation of Claim 53.

Patentability of Independent Claims 54 and 57

Claims 54 and 57 are rejected over a combination of Gain, the first NPL reference, Cecchi, and Bergman.

As discussed above, Bergman 8:35-50 ***does not*** disclose the concepts of a third material filling an opening as asserted in this rejection.

Also as discussed above, modifying Gain in view of Cecchi is unwarranted, because Gain's suitability as a training model responding to mechanical stresses is not enhanced by Cecchi's teaching, and the teaching of correct echogenic properties for a skull model is derived from applicants disclosure, not the prior art.

Accordingly, the rejection of independent Claim 54 under 35 U.S.C. § 103(a) should be withdrawn because the cited art does not teach or suggest all of the recitation of Claim 54.

Since dependent claims inherently include all of the recitation of the independent claims from which they ultimately depend, for at least the same reasons as noted above in connection with independent Claim 54, the rejection of dependent Claims 55 and 56 should also be withdrawn.

For similar reasons, Claim 57 is novel and non-obvious over the cited art. Accordingly, the rejection of independent Claim 57 under 35 U.S.C. § 103(a) should be withdrawn because the cited art does not teach or suggest all of the recitation of Claim 57.

Patentability of Independent Claim 58

Claim 58 was rejected because the specification did not support a "kit." Claim 58 has been amended to address this issue. Claim 58 recites a model and a plurality of materials enabling the model to be modified so that specific portions of the model can be differentiated in an ultrasound image, and the cited art does not teach or suggest an equivalent ultrasound training model.

Accordingly, the rejection of independent Claim 58 under 35 U.S.C. § 103(a) should be withdrawn because the cited art does not teach or suggest all of the recitation of Claim 58.

Conclusion

Upon consideration of the amendment to the claims and the Remarks set forth above, applicants respectfully request that the Examiner telephone them to discuss additional amendments, if the amendments have not addressed the Examiner's concerns with respect to 35 U.S.C. § 112.

Respectfully submitted,

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